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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,490	01/22/2002	Walter Prikoszovich	100-7664F/C5	6537

1095 7590 06/08/2007

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER
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WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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06/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/054,490	PRIKOSZOVICH, WALTER	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-58, 60, 64, 66-68 and 74-82 is/are pending in the application.
- 4a) Of the above claim(s) 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55, 56, 58, 60, 64, 66-68, 74-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152..

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/2/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55, 56, 58, 60, 64, 66-68, 74-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodmer et al (US 5,538,739) in view of GB 2,145,422 and Reiners et al (US 4,879,402).

Bodmer et al teach a matrix comprising octreotide (abstract, column 5 compound (a)). Linear polylactide -coglycolides of MW 25K-100K and a polydispersity of 1.2-2 are disclosed (column 8 lines 1-4). Star polymers are specified (column 8 line 35). Esters with glucose are disclosed (abstract). Lactide glycolide ratios of 60:40-50:60 are specified (column 8 lines 14-20). A method of making using that of GB 2,145,422 is specified (example 2). However, Bodmer et al do not teach removal of Sn octoate.

GB '422 teaches a method of making the polymer wherein the catalyst Sn octoate is preferred (page 2 line 41). Purification in the conventional manner is disclosed (page 2 line 47).

Reiners et al teach making a polymer using tin octoate (column 18 example 5). Filtration over active charcoal to obtain a colorless product is disclosed (column 18 lines 44-45).

It would have been obvious to one of ordinary skill to purify the polymer of Bodmer et al using activated charcoal in view of the teaching in GB '422 to use a conventional purification technique and further in view of the teaching in Reiners et al that, in a method of making a polymer using Sn octoate, the beneficial effect of purification to clarity is achieved using activated charcoal.

As to the particular degree of purification, an optimal such degree can be achieved by routine experimentation, especially in view of the Reiners et al teaching of purification to clarity.

Applicants argue that there is no motivation to combine. However, motivation has been provided. Applicants argue that Reiners is non-analogous art because it is directed to a polymer useful for dental materials (rather than drug delivery). However, it is directed to a synthesis of a polymer using tin octoate, analogous to applicants' synthesis. Applicants argue that Reiners' purification to clarity is not necessarily indicative of removal of the tin catalyst because the tin catalyst has very little effect on color, and further, that Reiners does not require charcoal. However, Reiners does teach charcoal for purification. One of ordinary skill recognizes that tin octoate will be removed because activated charcoal will bind to the two ethyl hexanoate chains that comprise the cation of tin octoate.

Applicants argue that none of the references teach purification to the claimed color. However, Reiners teaches purification to a colorless product, equivalent to or exceeding the claimed color standard. Lastly, applicants argue that the obvious combination does not teach all the claimed limitations to purity, in particular, metal ion content. That is, applicants argue, purification does not necessarily mean removal of all impurities. However, that argument is merely opinion.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richger, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500